SUMMARY

(In accordance with 40 CFR part 152, this summary is available for public release after registration)

STUDY TITLE

Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

DATA REQUIREMENTS

None

AUTHOR(S)

John P. Wright, Frank B. Selman, William L. Chen

STUDY COMPLETED ON

November 1, 2001

PERFORMING LABORATORY

Regulatory Laboratories - Indianapolis Lab
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, Indiana 46268-1054

LABORATORY STUDY ID

GH-C 5329

Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

SUMMARY

Dow AgroSciences (DAS) is providing comments on the Agency's human health assessment for oxyfluorfen. to address errors and inconsistencies found in the EPA document entitled: Oxyfluorfen. Human Health Risk Assessment. HED Chapter for the Reregistration Eligibility Decision (RED) Document. Registration Case No. 2490. Chemical No. 111601. DP Barcode D250186, and the attachments included therein. In these comments, DAS discusses areas where improvements in the risk assessment process could occur through alternate interpretations in methodology and correction of specific errors. DAS wishes to reserve the option for further error checking as study files become available. Based on the new cancer risk assessment guideline currently used by EPA, and scientific weight of evidence, oxyfluorfen should not be classified as a Class C animal carcinogen; a NOAEL and safety factor of 100 should be used instead of the Q* linear extrapolation. When realistic estimates for work activities, home owner uses, environmental dissipation rates, and water monitoring data are used, all oxyfluorfen use patterns result in exposures that are below the level of concern.

STUDY TITLE

Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

DATA REQUIREMENTS

None

AUTHOR(S)

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STUDY COMPLETED ON

November 1, 2001

PERFORMING LABORATORY

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GH-C 5329

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

Compound: Oxyfluorfen

Title: Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA Section 10 (d)(1)(A)(B), or (C).*

Company: Dow AgroSciences LLC

Company Agent: Barbara Kaminski

Title: Regulatory Manager

Signature: _____

Date: _____

*In the United States, the above statement supersedes all other statements of confidentiality that may occur elsewhere in this report.

THIS DATA MAY BE CONSIDERED CONFIDENTIAL IN COUNTRIES OUTSIDE THE UNITED STATES.

STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE STANDARDS

Title: Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

Study Initiation Date:	October 20, 2001	Study Completion Date:	November 1, 2001
Experimental Start Date:	October 25, 2001	Experiment Termination Date:	October 31, 2001

This report represents data generated after the effective date of the EPA FIFRA Good Laboratory Practice Standards.

United States Environmental Protection Agency
Title 40 Code of Federal Regulations Part 160
FEDERAL REGISTER, August 17, 1989

Organisation for Economic Co-Operation and Development
ISBN 92-64-12367-9, Paris 1982

This study does not meet requirements of 40 CFR Part 160.

Barbara Kaminski Sponsor Dow AgroSciences LLC	Date
Barbara Kaminski Submitter Dow AgroSciences LLC	Date
John P. Wright Study Director/Author Dow AgroSciences LLC	Date

QUALITY ASSURANCE STATEMENT

Compound: Oxyfluorfen

Title: Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

Study Initiation Date: October 20, 2001 Study Completion Date: November 1, 2001

NON-GLP STUDY

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Dow AgroSciences' Response to the U.S. EPA's Human Health Risk Assessment for Oxyfluorfen

ABSTRACT

Dow AgroSciences (DAS) is providing comments on the Agency's human health assessment for oxyfluorfen to address errors and inconsistencies found in the EPA document entitled: Oxyfluorfen. Human Health Risk Assessment. HED Chapter for the Reregistration Eligibility Decision (RED) Document. Registration Case No. 2490. Chemical No. 111601. DP Barcode D250186, and the attachments included therein. However, the preparation of these comments did not include an exhaustive examination of all data summarized within the Agency's document because DAS only recently acquired these products and is still in the process of transferring, cataloging, and archiving the data files. In these comments, DAS discusses areas where improvements in the risk assessment process could occur through alternate interpretations in methodology and correction of specific errors. DAS also wishes to reserve the option for further error checking as study files become available.

Based on the new cancer risk assessment guideline currently used by EPA, oxyfluorfen should not be classified as a Class C animal carcinogen. Furthermore, a NOAEL and safety factor of 100 should be used instead of the Q* linear extrapolation. The weight-of-the scientific evidence supports the conclusion that oxyfluorfen is not likely to be carcinogenic. Oxyfluorfen is not genotoxic (not mutagenic), there was not an increase in tumors in male and female rats and female mice. Only when liver hepatocellular (benign) adenomas and carcinomas in male mice are combined was there an increase in tumors of treated animals. Furthermore, it is well known that liver tumors in mice have little or no relevance to human cancer risk assessment. Since there was not an increase in hepatocellular adenomas and carcinomas in male and female rats in the chronic study, it can be concluded that oxyfluorfen is not likely to be carcinogenic.

Exposures from oxyfluorfen uses are below the level of concern for the Agency except for a few uses, principally certain occupational, residential, and calculated water concentrations, all of which include conservative assumptions regarding use patterns, activity levels, and model parameters. Much of this conservatism is acknowledged within the Agency documents themselves. Each of these concerns are mitigated by the degradation/dissipation of oxyfluorfen from the environment, the relatively small use areas, and realistic activity patterns for workers and residents. Further reductions in exposure estimates are derived from the use of average farm sizes, average days worked for chemical application vs. maximum available, realistic transfer coefficients for rough surfaces, and the use of water monitoring data. When realistic estimates of these parameters are included, all oxyfluorfen use patterns result in exposures that are below the level of concern.

INTRODUCTION

As requested by the EPA, Dow AgroSciences (DAS) is providing comments on the Agency's human health assessment for oxyfluorfen. These comments are intended to address errors and inconsistencies found in the EPA document entitled: Oxyfluorfen. Human Health Risk Assessment. HED Chapter for the Reregistration Eligibility Decision (RED) Document. Registration Case No. 2490. Chemical No. 111601. DP Barcode D250186, and the attachments included therein. However, the preparation of these comments did not include an exhaustive examination of all data summarized within the Agency's document. DAS only recently acquired these products through its acquisition of the Agricultural sector of Rohm and Haas and are still in the process of transferring, cataloging, and archiving the data files. The files needed for an extensive error checking were therefore unavailable within the 30-day comment period allowed. In these comments, DAS discusses areas where improvements in the risk assessment process could occur through alternate interpretations in methodology and correction of specific errors. DAS also wishes to reserve the option for further error checking, as study files become available.

GENERAL COMMENTS

The Agency's greatest concerns appear to be for occupational exposures, principally Christmas tree shearing, residential exposures from spot treatments to control weeds in driveway and patio cracks, and from model predictions of residues in drinking water. Each of these concerns includes conservative assumptions regarding use patterns, activity levels, and modeling scenarios for various components of human exposure. Much of this conservatism is acknowledged within the Agency document itself. These individual scenarios and their conclusions, however, are logically inconsistent with the conclusions that can be reached by a larger view of oxyfluorfen use patterns. For example, the assessments conclude that there is a greater risk from surface contact with a patio or driveway where the cracks have been sprayed with oxyfluorfen than from

spraying acres of orchards and vineyards. It also suggests that contact with the foliage while shearing Christmas trees with clippers and large knives poses an unacceptable risk when weeds around the base of the trees are controlled with oxyfluorfen. In a similar way, exposures from drinking water, based on the physical properties of oxyfluorfen and model predictions for drift and runoff, appear to exceed the exposures from direct application to food crops. Each of these concerns are mitigated by acknowledgement of the rapid photolytic degradation/dissipation of oxyfluorfen from the environment, the relatively small use areas, and realistic activity patterns for workers and residents.

SPECIFIC COMMENTS: OXYFLUORFEN, HUMAN HEALTH RISK ASSESSMENT. HED CHAPTER

Executive Summary

Page 5, Paragraph 5: As stated in this document and in "MEMORANDUM, Oxyfluorfen: Revised Occupational and Residential Non-Cancer and Cancer Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document [Case # 819447, PC Code 111601, DP Barcode D276147]" (page 31) residential exposure and risk assessments are conservative. Brick, concrete and similar surfaces are uncomfortable to play on. Adults would not be actively playing on this type of surface (if any) to the point of developing a TC of 16,700 and the attendant exposures calculated. Likewise, children would be similarly disinterested in creating the type of activity that would lead to the generation of exposures of the magnitude calculated.

Page 6 Paragraph 1: Delete the word *"both"* in the sentence beginning *"Risk assessments for aggregate…."*

Page 6 Paragraph 5 (Occupational exposure assessments): Short-term exposure would be expected to be most appropriate for the farmer mixer/loader and applicator scenarios and probably, due to the low likelihood of total market saturation, for the commercial worker as well.

Exposure and risk assessment should be calculated using the label minimum clothing requirements as a baseline. Then calculations could be made with extra PPE sequentially (i.e. gloves, dust mask, coverall, PF-10 respirator) or engineering controls added, as appropriate. For cancer risk calculations HED used average rates and acres per day, however, HED did not use average days worked for the commercial worker or farmer, but rather used maximum values for this portion of the algorithm. More appropriate assumptions would be based on 80 acres per day for the farmer but for an average farm size of 200 acres or less. Similarly, the commercial worker would not apply for the entire 30-day window of an application season unless a compound had managed 100% market insertion. Even in the corn-belt where one compound might have as much as 60% of the market commercial applicators rarely approach 30-days of applying a single compound.

Page 7 Paragraph 4: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low. The size of the trees, the amount of time spent shearing, and the very few number of applications made in a year all limit exposures. Overhead applications to Christmas trees could occur the year of transplanting and possibly the second year after transplanting. Thereafter spray applications are directed to the bases of the trees. The first year no shearing of the trees would occur and the only activity would be the straightening of trees which were not growing straight or the cutting of multiple trunks back to one trunk. Shearing when it begins the second year, consists of either a long thin knife or a power blade being used to shear new growth to promote multiple new growing points and to begin the shaping of the tree. Again, no physical contact occurs between the worker and the tree. Subsequent trimmings during the second season and following seasons would again result in minimal to no exposure due to the type of equipment used to trim the trees. It would be possible to brush against the trees with one's legs once they grow enough to close in the middles but at this time most weeds would be prevented from germinating due to the shading effect of the thick tree canopy and application of oxyfluorfen is unlikely.

Page 8 Paragraph 8 and 9: DAS agrees with HED that the 10 and 30 days used for assessment of risk to farmers and to commercial workers is appropriate as a screen, but should be refined for decision making. As stated above DAS also concurs that Christmas tree shearing risk assessments are conservative.

DAS also agrees with HED that the residential post application exposure estimates are conservative. The amount of contact with hard abrasive surfaces is probably much less than indicated by the transfer coefficients and it is possible that less compound is available for transference due to the absorptive natures of porous brick and concrete surfaces. The time frames calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Dietary Exposure

Food, Page 21: "there are some uncertainties associated with the exposure estimates as follows: (i) the use of ½ LOQs for field trial residue values…"
The Agency states that all field trials had non-detectable residues, as did the PDP monitoring data. The Agency therefore should use ½ LOD for all residues after adjustment for percent market share.

Surface Water Monitoring

Page 22: "EFED believes the limitation of oxyfluorfen use to non-bearing citrus precludes large portions of watersheds from being treated simultaneously…"

DAS agrees with this statement and further purports that the same logic can be applied to any orchard situation. The likelihood of entire watersheds being treated with oxyfluorfen is very remote, considering the areas where orchards occur, the periodicity of applications, and the prevalence of other weed control options. With the assumptions of watershed wide treatments, spray drift, erosion of significant amounts of soil immediately following application, no vegetative buffer zones, and no photo-degradation of the product results in very conservative exposure estimates for drinking water. Indeed, a refinement of the PRZM/EXAMS input data decreased the predictions 65% while the limited monitoring data available showed water concentrations 10 times lower.

Spray Drift

Page 28: Spray drift label language is under active discussion among the Agency, SDTF, and individual registrants. Currently no agreements have been reached on label languages or product specific label requirements.

Residential Post Application Exposure and Risk

Policy No. 12 (Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments) lists TCs of 16,700 cm^2/hr for adults and 6,000 cm^2/hr for children. DAS agrees with HED, that based on the type of activity which would most likely occur on a hard abrasive surface and the potential absorptive characteristics of brick and concrete these are conservative values. The time frames calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Occupational Handlers/Applicators

Page 34 Bullet 4 and Page 35 Bullets 9, and 10: Average days worked should also be considered as well as average application rates and daily acreage for use in the cancer calculations. The maximum screening values of 10 and 30 days worked for farmers and commercial applicators respectively should not be used for calculation of cancer risks but a value which represents the average days on which a compound would be handled, should be used. For farmers this would likely be 80 acres per day for the number of days required to treat the average size farm. For commercial applicators the value would be much shorter and would represent the average number of days in an application window on which they would apply a given compound not the maximum days in a region for which a crop could be treated.

Page 35 Bullets 13, and 14: Baseline calculations of exposure and risk should represent the minimum label clothing requirements for clothing and not a scenario which is not relevant to the compound being evaluated. If further refinement is required, the next scenario should build on the Baseline in such a way that each incremental increase in PPE is covered (i.e. gloves, dust mask, coverall, PF-10 respirator) or until engineering controls are necessary.

Exposure and Risk Estimates for Non-Cancer Effects

Page 35: Since the PPE requirements listed on the labels range from baseline to double layer and most of them require either water proof or chemical resistant gloves, a scenario should be developed which bridges between the Baseline and the Single Layer PPE. At that point it would be evident how much impact the respiratory protection afforded in the Single Layer PPE has on the exposure and risk calculations.

Exposure and Risk Estimates for Cancer Effects

Page 36: As stated previously, number of days worked should represent the average days that an average farmer or commercial applicator would handle a given compound, not the maximum days that a crop could be treated. Also, since labels run the gamut from baseline to double layer

protection, there should be a bridge between Baseline and Single Layer PPE to indicate the importance of gloves as mitigation for those scenarios which do not pass Baseline but do not require respiratory protection to exceed levels of concern.

Transfer Coefficients

Page 41, Table 18, Transfer Coefficient for Christmas Shearing: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low. Overhead applications to Christmas trees could occur the year of transplanting and possibly the second year after transplanting. The first year no shearing of the trees would occur and the only activity would be the straightening of trees which were not growing straight or the cutting of multiple trunks back to one trunk. Shearing when it begins the second year, consists of either a long thin knife or a power blade being used to shear the new growing points to promote multiple new growing points and to begin the shaping of the tree. Again, no physical contact occurs between the worker and the tree. Subsequent trimmings during the second season and following seasons would again result in minimal to no exposure due to the type of equipment used to trim the trees. It would be possible to brush against the trees with one's legs once they grow large enough to close in the middles. At this time, most weeds would be prevented from germinating due to the shading effect of the thick tree canopy, thus making the use of a herbicide application in the row unnecessary.

Exposure and Risk Estimates for Cancer

Page 43: DAS agrees with HED that the use of 10 days post application for private growers and 30 days for commercial workers is conservative. "Chemical mowing" occurs as needed, usually beginning early in the spring, and shearing may not even occur at a time that would overlap with the application. The rapid dissipation (half-life 0.36 – 2 days) of oxyfluorfen from conifer seedlings would further reduce the possibility of exposures. The unlikely occurrence of same-day spraying and shearing operations, rapid dissipation rates, and limited, actual contact with the trees by the person doing the shearing makes significant exposures very unlikely.

Appendix D

Table D4: footnote "a" for the column titled "Data Confidence" should be "A". *Occupational Residential…* should be changed to "Outdoor Residential Exposure Task Force"

SPECIFIC COMMENTS: OXYFLUORFEN – REPORT OF THE HAZARD IDENTIFICATION ASSESSMENT REVIEW COMMITTEE

General Comment

Based on the new cancer risk assessment guideline currently used by EPA, oxyfluorfen should not be classified as a Class C animal carcinogen. Furthermore, a NOAEL and safety factor of 100 should be used instead of the Q* linear extrapolation.

Specific Comments

HIARC Pgs. 29 & 33: The requirement for a 28-day inhalation study should be deleted. The absence of the study is not considered a data gap since it is not required under 40CFR, Part 158.340. A guideline is not available under OPPTS Series 870.

EPA classified oxyfluorfen as a Class C animal carcinogen with a Q* linear extrapolation cancer risk of 7.23×10^{-2}. This was based on an increase of combined liver hepatocellular adenomas and carcinomas in the high dose of 200 ppm in chronically-treated male mice. There was not an increase in tumors in female mice and in both male and female rats treated with oxyfluorfen for a life-time. The cancer classification used by EPA for oxyfluorfen was based on a 1986 methodology (EPA, 1986) which has now been replaced by a new revised cancer risk assessment guideline (Sonich-Mullin, C.*, et al*., 2001). Dow AgroSciences contends that according to the new revised cancer risk assessment guideline, oxyfluorfen is not likely to be a carcinogen. A

NOAEL and safety factor of 100 should be used instead of the Q* linear extrapolation for dietary, residential and worker risk assessments.

The weight-of-the scientific evidence supports the conclusion that oxyfluorfen is not likely to be carcinogenic is as follows:

- Oxyfluorfen is not genotoxic i.e. it is not mutagenic.
- Carcinogenicity studies have shown that there was no increase in tumors in male and female rats and female mice.
- Only in male mice, only at the high dose, and only when liver hepatocellular (benign) adenomas and carcinomas are combined was there an increase in tumors of treated animals. This is most likely due to a non-genotoxic mode of action where a threshold level of exposure can be determined.
- It is well known that mice have a high spontaneous background incidence of liver tumors and these tumors have little or no relevance to human cancer risk assessment.
- Toxicologists generally agree that induction of rat liver tumors is more relevant to humans. Since there were no increase in hepatocellular adenomas and carcinomas in male and female rats in the chronic study, it can be concluded that oxyfluorfen is not likely to be carcinogenic.

SPECIFIC COMMENTS: OXYFLUORFEN. ANTICIPATED RESIDUES AND DIETARY EXPOSURE ANALYSES FOR THE HED HUMAN HEALTH RISK ASSESSMENT.

Residue Information

Page 6-7: The Agency states that there were no detectable residues on the commodities, and "in general all residues were non-detectable at an LOD of 0.01 ppm", yet they used ½ the LOQ in calculation of anticipated residues. PDP lists LOD values of from 0.01 to 0.003 ppm. Why was ½ LOQ used instead of ½ LOD?

Additional Comments Offered on Drinking Water Exposures

The drinking water exposure assessment used by the Agency calculated a DWLOC from PRZM/EXAMS predicted water concentrations. Such calculations are highly dependent upon the input assumptions and are conservative by nature. Using the 36 year mean water concentration of 5.7 ppb, and the water consumption data available in DEEM, the following exposures are calculated:

Table I. PRZM/EXAMS assumption of 5.7 ppb water concentration

Population Sub-group	**Total Exposure mg/kg-Bwt/day**	**Lifetime Risk Q*= .0732**
U.S. Population (total)	0.000165	1.21E-05
All infants (< 1 year)	0.000612	4.48E-05
Nursing infants	0.000183	1.34E-05
Non-nursing infants	0.000771	5.65E-05
Children 1-6 yrs	0.000250	1.83E-05
Children 7-12 yrs	0.000169	1.24E-05
Females 13-19 (not preg or nursing)	0.000129	9.47E-06
Females 20+ (not preg or nursing)	0.000154	1.13E-05
Females 13-50 yrs	0.000150	1.10E-05
Females 13+ (preg/not nursing)	0.000137	1.00E-05
Females 13+ (nursing)	0.000167	1.22E-05
Males 13-19 yrs	0.000134	9.81E-06
Males 20+ yrs	0.000143	1.05E-05
Seniors 55+	0.000146	1.07E-05

Using the alternative Tier II surface water-derived drinking water concentrations (2.2 ppb) from Snyder and Carbone (2001), which come from model runs using the correct PRZM/EXAMS input parameters gives the following exposure estimates:

Table II. Revised PRZM/EXAMS estimate of 2.2 ppb water concentration

Population Sub-group	**Total Exposure mg/kg-Bwt/day**	**Lifetime Risk Q*= .0732**
U.S. Population (total)	0.000064	4.67E-06
All infants (< 1 year)	0.000236	1.73E-05
Nursing infants	0.000070	5.16E-06
Non-nursing infants	0.000298	2.18E-05
Children 1-6 yrs	0.000096	7.05E-06
Children 7-12 yrs	0.000065	4.78E-06
Females 13-19 (not preg or nursing)	0.000050	3.66E-06
Females 20+ (not preg or nursing)	0.000059	4.34E-06
Females 13-50 yrs	0.000058	4.24E-06
Females 13+ (preg/not nursing)	0.000053	3.87E-06
Females 13+ (nursing)	0.000065	4.73E-06
Males 13-19 yrs	0.000052	3.79E-06
Males 20+ yrs	0.000055	4.04E-06
Seniors 55+	0.000056	4.13E-06

Alternatively, the limited water monitoring data suggests a greatly reduced water concentration. The cited USGS study appears to be quite representative of the rainy season surface water suspended sediment loading during the peak use period of oxyfluorfen in California's Central Valley, the highest intensity use area. The estimated maximum concentration of 0.27 µg/L is probably too high because of the organic matter content of the sediment, yet it is at least an order of magnitude lower than the alternative proposed concentrations coming from corrected Tier II modeling. This order of magnitude discrepancy between predicted and observed concentrations

is typical for most pesticides. Therefore, DAS proposes that the data considered as reliable information suitable for FQPA human health risk assessment should be the monitoring data supporting a concentration no greater than 0.27 μg/L.

Using this new water concentration value reduces the cancer risk assessment to below the level of concern of $1X10^{-6}$:

Table III. Revised estimate of 0.27 ppb water concentration from monitoring data.

Population Sub-group	Total Exposure mg/kg-Bwt/day	Lifetime Risk Q*= .0732
U.S. Population (total)	0.000008	5.73E-07
All infants (< 1 year)	0.000029	2.12E-06
Nursing infants	0.000009	6.33E-07
Non-nursing infants	0.000037	2.67E-06
Children 1-6 yrs	0.000012	8.66E-07
Children 7-12 yrs	0.000008	5.87E-07
Females 13-19 (not preg or nursing)	0.000006	4.49E-07
Females 20+ (not preg or nursing)	0.000007	5.33E-07
Females 13-50 yrs	0.000007	5.21E-07
Females 13+ (preg/not nursing)	0.000006	4.75E-07
Females 13+ (nursing)	0.000008	5.80E-07
Males 13-19 yrs	0.000006	4.65E-07
Males 20+ yrs	0.000007	4.96E-07
Seniors 55+	0.000007	5.06E-07

SPECIFIC COMMENTS: REVISED OCCUPATIONAL AND RESIDENTIAL NON-CANCER AND CANCER EXPOSURE AND RISK ASSESSMENT

DAS would like to compliment HED on a well written, concise and easy to follow exposure assessment. Responses to the exposure and risk assessments contained in the MEMORANDUM will be presented in the order in which they appear in the MEMORANDUM.

Occupational Handler/Applicator Exposure and Risk Estimates

Page 2 Paragraph 3: Since Q* is a population statistic, calculations of cancer risks for custom handlers/applicators should be based on an average of the number of days a custom applicator is expected to handle a single compound. It should not be based on the maximum number of days for which an application could be made to a crop.

Post-Application Occupational Exposure and Risk Estimates

Page 3 Paragraph 2,3: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low. Overhead applications to Christmas trees could occur the year of transplanting and possibly the second year after transplanting. The first year no shearing of the trees would occur and the only activity would be the straightening of trees which were not growing straight or the cutting of multiple trunks back to one trunk. Shearing when it begins the second year, consists of either a long thin knife or a power blade being used to shear the new growing points to promote multiple new growing points and to begin the shaping of the tree. Again, no physical contact occurs between the worker and the tree. Subsequent trimmings during the second season and following seasons would again result in minimal to no exposure due to the type of equipment used to trim the trees. It would be possible to brush against the trees with one's legs once they grow enough to close in the middles but at this time most weeds would be prevented from germinating due to the shading effect of the thick tree canopy making the use of a herbicide treatment unnecessary.

Residential Post Application and Risk Estimates

Page 3 Paragraph 1: Policy No. 12 (Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments) lists TCs of 16,700 cm^2/hr for adults and 6,000 cm^2/hr for children. DAS agrees with HED, that based on the type of activity which would most likely occur on a hard abrasive surface and the potential absorptive characteristics of brick and concrete these are conservative values. The time frames calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Risk Characterization

Page 4 Paragraphs 1,2,3: DAS agrees with HED that the 10 and 30 days used for assessment of risk to farmers and to commercial workers is appropriate as a screen, but should be refined for decision making.

As stated above DAS also concurs that Christmas tree shearing risk assessments are conservative.

DAS also agrees with HED that the residential post application exposure estimates are conservative. The amount of contact with hard abrasive surfaces is probably much less than indicated by the transfer coefficients and it is possible that less compound is available for transference due to the absorptive natures of porous brick and concrete surfaces.

Risk Mitigation

Page 5: Most of the labels include the requirement for gloves while mixing and loading, those without should be looked at and improved if possible. The single layer calculations in this assessment were calculated using respiratory protection but since glove and dust mask were not added separately to the baseline, it is not clear if the full single layer PPE is necessary. As stated above, even though the Policy 3.1 TC results in high exposure, shearing of Christmas trees results in almost no contact with the tree and therefore creates little potential for actual exposure. Residential spot treatment rates are higher so as to offer residual control of weeds in those areas treated. Since the exposure calculated for this scenario is admittedly very conservative, it should not be necessary to reduce the rates.

Exposure Assumptions and Data Sources

Page 12 Bullet 4: Average days worked should also be considered as well as average application rates and daily acreage for use in the cancer calculations.

Page 13 Bullets 9 and 10: The maximum screening values of 10 and 30 days worked for farmers and commercial applicators respectively should not be used for calculation of cancer risks. A value, which represents the average days on which a compound would be handled, should be used. For farmers this would likely be 80 acres per day for the number of days required to treat the average size farm. For commercial applicators the value would be much shorter and would represent the average number of days in an application window on which they would apply a given compound not the maximum days in a region for which a crop could be treated.

Scenarios of Concern With PPE to Mitigate Risks

Page 16: While the single layer PPE results in MOEs which are of concern the single layer PPE includes dust mask protection which may not be necessary when gloves are added to the baseline clothing scenario.

Occupational Applicator Exposure and Risk Estimates for Cancer

Page 17 Paragraph 2: For calculating cancer risk the average days worked (instead of the maximum) should be used as well as the average application rates and acres treated per day. Line 3 should read "instead of the maximum".

Exposure Data Sources, Assumptions and Transfer Coefficients

Data Sources

Page 20: Typo in paragraph 4 line 3 "by adding a 5 ml" should read "by adding 5 ml".

Assumptions

Page 21 Bullets 4 and 5: Average days worked should also be considered as well as average application rates and daily acreage for use in the cancer calculations.

Transfer Coefficients

Table 12- Post Application Exposure Scenarios and transfer Coefficients: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low. Overhead applications to Christmas trees could occur the year of transplanting and possibly the second year after transplanting. The first year no shearing of the trees would occur and the only activity would be the straightening of trees which were not growing straight or the cutting of multiple trunks back to one trunk. Shearing when it begins the second year, consists of either a long thin knife or a power blade being used to shear the new growing points to promote multiple new growing points and to begin the shaping of the tree. Again, no physical contact occurs between the worker and the tree. Subsequent trimmings during the second season and following seasons would again result in minimal to no exposure

due to the type of equipment used to trim the trees. It would be possible to brush against the trees with one's legs once they grow enough to close in the middles but at this time most weeds would be prevented from germinating due to the shading effect of the thick tree canopy making an herbicide treatment unnecessary.

Calculation Methodology for Post Application Exposures

Line 2: Typo (ug/cm^2 of leave area) should read (ug/cm^2 of leaf area).

Exposure and Risk Estimates for Non-Cancer Effects

Table 13 - Oxyfluorfen Post Application Non-Cancer Risks, Conifer Trees – Shearing: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low.

Exposure and Risk Estimates for Cancer

Table 14: Post Application Cancer Risks for Commercial Workers and Table 15 – Post Application Cancer Risk Summary for Private Growers, Conifer Trees – Shearing: While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low.

Scenarios, Data Sources, and Assumptions

Data Sources: Page 28, Transfer Coefficient cm^2/hr: Policy No. 12 (Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessments) lists TCs of 16,700 cm^2/hr for adults and 6,000 cm^2/hr for children. DAS agrees with HED, that based on the type of activity which would most likely occur on a hard abrasive surface and the potential absorptive characteristics of brick and concrete these are conservative values. The time frames

calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Assumptions, Page 29, Bullet 1: Currently reads "10% of the applied amount would deposit on the surface and would be transferable". DAS suggests that it was meant to read "10% of the applied amount would be transferable".

Residential Post Application Exposure and Risk Estimates for Non-Cancer Effects

Brick, concrete and similar surfaces are uncomfortable to play on. Adults would not be actively playing on this type of surface (if any) to the point of developing a TC of 16,700 and the attendant exposures calculated. Likewise, children would be similarly disinterested in creating the type of activity that would lead to the generation of exposures of the magnitude calculated on these surfaces. The time frames calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Residential Post Application Exposure and Risk Estimates for Cancer

Brick, concrete and similar surfaces are uncomfortable to play on. Adults would not be actively playing on this type of surface (if any) to the point of developing a TC of 16,700 and the attendant exposures calculated. Likewise, children would be similarly disinterested in creating the type of activity that would lead to the generation of exposures of the magnitude calculated on these surfaces. The time frames calculated by the agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for a use which involves treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Occupational Risk Characterization

Bullet 1: Days applied per year should also be an average rather than a high end value for both the farmer and for the commercial worker.

Occupational Handler Risk Characterization

While single layer PPE was sufficient to achieve MOEs of greater than 300 and cancer risk below 1 x 10^{-4} for all handler/applicator scenarios, no baseline plus gloves scenario was calculated. This might have achieved the same results without respiratory protection.

Post-Application Worker Risk Characterization

DAS agrees with HED that the 10 and 30 days used for assessment of risk to farmers and to commercial workers is appropriate as a screen for short-term risk assessment, but should be refined for decision making, and feels that when used for cancer risk assessments these values should be replaced with average days worked for both the farmer and the commercial worker.

While shearing of Christmas trees is considered in this document to be the greatest risk for workers based on the use of current TC values for this work procedure, actual exposure from shearing of Christmas trees is extremely low. Overhead applications to Christmas trees could occur the year of transplanting and possibly the second year after transplanting. The first year no shearing of the trees would occur and the only activity would be the straightening of trees which were not growing straight or the cutting of multiple trunks back to one trunk. Shearing, when it begins the second year, consists of either a long thin knife or a power blade being used to shear the new growing points to promote multiple new growing points and to begin the shaping of the tree. Again, no physical contact occurs between the worker and the tree. Subsequent trimmings during the second season and following seasons would again result in minimal to no exposure due to the type of equipment used to trim the trees. It would be possible to brush against the trees with one's legs once they grow enough to close in the middles, but at this time, most weeds would be prevented from germinating due to the shading effect of the thick tree canopy. DAS concurs that Christmas tree shearing risk assessments are conservative based on agronomic and work pattern considerations making herbicide applications unnecessary.

Residential Risk Characterization

DAS agrees with HED that the residential post application exposure estimates are conservative. The amount of contact with hard abrasive surfaces is probably much less than indicated by the transfer coefficients and it is possible that less compound is available for transfer due to the absorptive natures of porous brick and concrete surfaces. The time frames calculated by the

agency for acceptable exposure to occur are the result of dose levels at or above 200 ug/kg/day of oxyfluorfen. Other residential compounds with more extensive uses (i.e. turf broadcast, crack and crevice, garden) have been measured in the general public using biomonitoring. The results of this monitoring are available publicly and indicate average exposures of less than 1 ug/kg/day. Thus, a calculated exposure dose of 200 ug/kg/day for treating driveways and patios is apparently extremely high. Therefore, HED's assertion that this is a conservative assessment is valid.

Risk Mitigation

Bullet 1: Most of the labels include the requirement for gloves while mixing and loading, those without should be looked at and improved if possible. The single layer calculations in this assessment were calculated using respiratory protection but since glove and dust mask were not added separately to the baseline, it is not clear if the full single layer PPE is necessary.

Bullet 2: As stated above, even though the Policy 3.1 TC results in high exposure, shearing of Christmas trees results in almost no contact with the tree and therefore creates little potential for actual exposure.

Bullet 3: Residential spot treatment rates are higher so as to offer residual control of weeds in those areas treated. Since the exposure calculated for this scenario is admittedly very conservative, it should not be necessary to reduce the rates.

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